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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/142,613	04/19/1999	KOICHI ISHIGURO	1416/OP551PC	2418

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WENDEROOTH LIND & PONACK
2033 K STREET NW SUITE 800
WASHINGTON, DC 20006

EXAMINER

TURNER, SHARON L

ART UNIT	PAPER NUMBER
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1647

28

DATE MAILED: 02/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/142,613

Applicant(s)

ISHIGURO ET AL.

Examiner

Sharon L. Turner

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 6-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1 and 6-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Continued Prosecution Application

1. The request filed on 12-10-01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/142,613 is acceptable and a CPA has been established. An action on the CPA follows.
2. The amendment and declaration filed 11-15-02 have been entered into the record and have been fully considered.
3. Claims 1 and 6-24 are pending.

Election/Restriction

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1, 6, 8, 18-23, drawn to antibodies to a partial peptide wherein the antibody specifically recognizes said phosphorylated serine and reagent kit classified in class 530, subclass 387.1.
 - II. Claims 10-16, drawn to antibodies to a partial peptide wherein the antibody specifically recognizes said phosphorylated serine and one or more phosphorylation sites at other positions, and reagent kit classified in class 530, subclass 387.1.
 - III. Claims 7, 9, and 24 drawn to a method of detecting Alzheimer's with the reagent kit of Group I, classified in class 435, subclass 300.
 - IV. Claim 17, drawn to a method of detecting Alzheimer's with the reagent kit of Group II, classified in class 530 subclass 300.
5. The inventions are distinct, each from the other because of the following reasons:
6. Claims 7, 9 and 24 link Inventions I and III. The restriction requirement among

the linked inventions is subject to the nonallowance of the linking claim(s), claims 6 and 23. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In *re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

7. Inventions I and II are related as products. The products are distinct as the antibodies are characterized by different epitopic specificity, bind to different peptides and are capable of different functions and effects as characterized by their different specificity. A search for any one of the antibodies is not co-extensive with a search for any other. Moreover, a reference to any one element is not necessarily a reference to any other.

8. Thus, search and examination of the multiple patentably distinct antibodies in a single application places an undue burden on the Examiner and the Office's resources.

9. Inventions III and IV are related as processes. The processes are distinct as they use different reagents as set forth above and thus comprise different steps,

outcomes and perform different functions. Thus, the processes are distinct each from the other.

10. Inventions I-II and III-IV are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the processes of detection can be used with any of the products of group I, II or with an antibody to beta amyloid and the products of group I or II could alternatively be used in an assay for tau inhibitors.

11. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and recognized divergent subject matter restriction for examination purposes as indicated is proper.

12. Because these inventions are distinct for the reasons given above and the search required for each of the groups is not required for any other group, restriction for examination purposes as indicated is proper.

13. This application contains claims directed to the following patentably distinct species of the claimed invention:

In Groups I and III, species of peptides selected from a) SEQ ID NO:2, b) partial peptides of 1 to 7 amino acids in length, c) partial peptides of 3-5 amino acids in length.

In Group II and IV, species A) phosphorylation sites, a) serine 198, b) serine 202,

c) threonine 205, d) threonine 231, e) serine 235, f) serine 262, g) serine 396, h) threonine 403, i) serine 404, j) serine 409, k) serine 412, l) serine 413 and m) serine 422 and species B) peptides of a) 1 to 7 amino acids in length, b) 3 to 5 amino acids in length and c) SEQ ID NO:5.

If Applicant should elect Group I or Group III, Applicant should elect a single species of peptides of a)-c) as set forth above for initial prosecution on the merits.

If Applicant should elect Group II or IV, Applicant should elect a single species from group A) phosphorylation sites and B) peptides as set forth above for initial prosecution on the merits.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species as set forth above for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 10, 16, 18 and 23 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the

elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

14. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

15. Because these inventions are distinct for the reasons given above and the search required for any Group is not required for any other Group, restriction for examination purposes as indicated is proper.

16. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

17. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

18. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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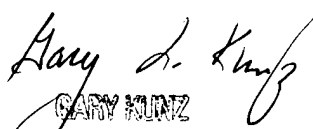
remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

19. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
February 4, 2003


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600